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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 09/819,097 | 03/05/2001 | Andrea Margaret Douglas | 11375Z | 6127 |
| 7590 | 12/02/2003 | | EXAMINER | |
| Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530 | | | DEBERRY, REGINA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/819,097 | DOUGLAS ET AL. | |
| | Examiner | Art Unit | |
| | Regina M. DeBerry | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 August 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30-36 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 25 August 2003 has been entered in full.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the specification as set forth at pages 4-5 of the previous Office Action (21 February 2003) is *withdrawn* in view of the amendment (25 August 2003).

The objection to claims 30 and 33-36 as set forth at page 4 of the previous Office Action (21 February 2003) is *withdrawn* in view of Applicant's arguments, however, only oncostatin M (the elected species) will be considered. Applicant maintains that the claims will be restricted to the elected species only when no generic claim is finally held to be allowable. At this point, the Examiner has not identified any prior art that would render the generic claims (claims 30-31) unpatentable. The only non-final rejection of the generic claims is raised under 35 U.S.C. 112, first paragraph. Applicant states as it is believed that the generic claims are fully enabled, as set forth below, it is respectfully submitted that Applicants are entitled to consideration of species in addition to the elected species of oncostatin M. Accordingly, withdrawal of the objection to claims 30 and 33-36 is respectfully requested.

Contrary to Applicant's assertion, the MPEP states that Applicant is required under 35 U.S.C. 121 to elect a single disclosed species ***for prosecution on the merits*** to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

Claims 30-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is set forth at pages 5-9 of the previous Office Action (21 February 2003).

Applicant states that the specification provides exemplification of the inhibitory effects of OSM on the proliferation of malignant breast cancer cells *in vitro*. Applicants submit that the present application recognizes for the first time that cytokines, such as oncostatin M (OSM), interleukin-6 (IL-6), interleukin-1 1 (IL-11), leukemia inhibitory factor (LIF) and epidermal growth factor (EGF), have inhibitory effects on the proliferation of malignant breast cancer cells. The specification provides a thorough characterization of the inhibitory effects of OSM on the proliferation of malignant breast cancer cell *in vitro*, including inhibitory doses, and the effects on cell cycle, cell morphology and the expression of various cell surface receptors. Applicants maintain that those skilled in the

art would consider that the *in vitro* characterizations provided in the specification are reasonably correlated to inhibitory effects of the selected cytokines on the proliferation of malignant breast cancer cells *in vivo*. Applicants contend that there is no evidence that the obstacles are not insurmountable. Moreover, some experimentation is permissible. Applicants cite *In re Wands*. Applicants state that necessary experimentation is not determinative of the question of enablement; only undue experimentation is fatal under the provisions of 35 U.S.C. 112, first paragraph. Applicants submit that the specification has provided sufficient guidance to those skilled in the art to practice the claimed methods without undue experimentation.

Applicants' arguments have been fully considered but not deemed persuasive. The state of the prior art (what one skilled in the art would have known at the time the application was filed) provides evidence for the degree of predictability in the art and is related to the amount of direction needed in the specification. The more that is known in the prior art about the nature of the invention, the more predictable it is and the less information is needed. The Examiner cited various scientific references to demonstrate the problems with correlating *in vitro* data with *in vivo* treatments and the unpredictability regarding anti-cancer drug discovery for cancer treatments. A considerable amount of time is permissible *if* it is merely routine or if the skilled artisan is given sufficient direction or guidance. In the instant case, the experimentation is not routine and Applicant has provided little or no guidance relating to methods of inhibiting the proliferation of malignant breast cancer cells *in mammals* comprising administering oncostatin M (OSM). Based on the factors presented, it would require an indeterminate quantity of

fundamentally unpredictable investigational experimentation of the skilled artisan to make and/or use the instant invention. Such experimentation would be undue for one skilled in this art. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


RMD
November 24, 2003


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600